

## Notice of Allowability

Application No.

10/054,665

Applicant(s)

ENGELHARDT ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment and Terminal Disclaimer filed 9/20/04.

2. ☒ The allowed claim(s) is/are 40-60.

3. ☒ The drawings filed on 9/20/04 and 1/22/02 are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 9/20/04

4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 10/29/04.

7. ☒ Examiner's Amendment/Comment

8. ☐ Examiner's Statement of Reasons for Allowance

9. ☐ Other \_\_\_\_\_.

### Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Janet E. Embretson on 10/29/04.

The application has been amended as follows:

#### In the **Claims**:

Claim 59 (Currently amended) A first composition comprising:

a first adeno-associated virus vector comprising linked:

a) i) a first nucleic acid segment comprising a s'-inverted terminal repeat of adeno-associated virus;

ii) a second nucleic acid segment comprising a portion of a gene which includes a transcriptional regulatory region;

iii) a third nucleic acid segment comprising a splice donor site; and

iv) a fourth nucleic acid segment comprising a 3'-inverted terminal repeat of adeno-associated virus;

[which first vector, in the presence of] and a second composition comprising a second adeno-associated virus vector comprising linked:

b) i) a first nucleic acid segment comprising a 5' -inverted terminal repeat of adeno-associated virus;

ii) a second nucleic acid segment comprising a splice acceptor site;

iii) a third nucleic acid segment comprising a portion of a gene which together with the nucleic acid segment of a)ii) comprises a gene comprising an open reading frame which encodes a functional polypeptide;

iv) a fourth nucleic acid segment comprising a 3' -inverted terminal repeat of adeno-associated virus;

which vectors in a host cell [yields] yield a RNA transcript which comprises sequences from the first adeno- associated virus vector linked to sequences from the second adeno-associated virus vector, which sequences are positioned so that the splice donor site is 5' to the splice acceptor site, and which transcript is spliced to a mRNA which encodes the functional protein.

Claim 60 (Currently amended) A first composition comprising:

a first adeno-associated virus vector comprising linked:

- a) i) a first nucleic acid segment comprising a 5' -inverted terminal repeat of adeno-associated virus;
- ii) a second nucleic acid segment comprising a splice acceptor site;
- iii) a third nucleic acid segment comprising a portion of a gene; and
- iv) a fourth nucleic acid segment comprising a 3'-inverted terminal repeat of adeno-associated virus;

[which first vector, in the presence of] and a second composition comprising a second adeno-associated virus vector comprising linked:

b) i) a first nucleic acid segment comprising a 5'-inverted terminal repeat of adeno-associated virus;

ii) a second nucleic acid segment comprising a portion of a gene which together with the nucleic acid segment of a)iii) comprises a gene comprising an open reading frame which encodes a functional polypeptide, wherein the portion of the gene of b)ii) includes a transcriptional regulatory region;

iii) a third nucleic acid segment comprising a splice donor site;

iv) a fourth nucleic acid segment comprising a 3'-inverted terminal repeat of adeno-associated virus;

which vectors in a host cell [yields] yield a RNA transcript which comprises sequences from the first adeno-associated virus vector linked to sequences from the second adeno-associated virus vector, which sequences are positioned so that the splice donor site is 5' to the splice acceptor site, and which transcript is spliced to a mRNA which encodes the functional protein.

In the **Specification:**

On Page 9, line 22, after "Figure 1" insert --(Parts A-D)--.

On Page 10, line 1, after "Figure 2" insert --(Parts A-E)--.

On Page 10, line 15, delete "(Panel C)" and substitute --(Panels C-E)--.

On Page 10, line 24, after "Figure 3" insert --(Parts A-F)--.

On Page 11, line 20, after "Figure 4" insert --(Parts A-C)--.

On Page 12, line 17, after "Figure 5" insert --(Parts A-C)--.

On Page 13, line 21, after "Figure 7" insert --(Parts A-D)--.

On Page 14, line 18 after "Figure 8" insert --(Parts A-B)--.

On Page 15, line 24, after "Figure 10" insert --(Parts A-C)--.

On Page 16, line 26, after "Figure 14" insert --(Parts A-C)--.

On Page 17, line 11, after "Figure 15" insert --(Parts A-D)--.

On Page 18, line 6, after "Figure 16" insert --(Parts A-C)--.

On Page 18, line 23, after "Figure 17" insert --(Parts A-D)--.

On Page 19, line 7, after "Figure 18" insert --(Parts A—D)--.

On Page 20, line 6, after "Figure 19" insert --(Parts A-B)--.

The above amendments to the Brief Description of the Drawings were necessary to indicate that the Figures are comprised of different panels. The Brief Description of Figure 2 was further amended (on line 15) to indicate that the sequence analysis of the six clones is shown in Panels C-E because the newly submitted (on 9/20/04) Figure 2 divided Panel C into Panels C-E.

The related applications cited by applicants in the IDS filed 9/20/04 have been considered by the examiner.

The Terminal Disclaimer filed 9/20/04 has been approved.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571)

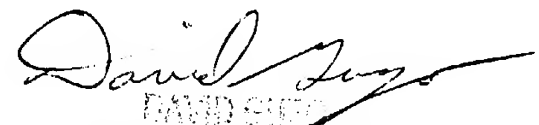
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272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
October 29, 2004

  
DAVID GUZO  
PRIMARY EXAMINER